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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,015	02/26/2004	Tomoaki Hoshino	021310B	3534

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EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/786,015	HOSHINO, TOMOAKI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/257,965.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED OFFICE ACTION

Applicant's preliminary amendment filed on 26 February 2004 is acknowledged and entered. Following the amendment, the original claims 1-26 and 29-31 are canceled.

Currently, claims 27 and 28 are pending and under consideration.

#### **Formal Matters:**

##### ***Information Disclosure Statement***

Applicant's IDS submitted on 2/26/2004 is acknowledged and has been considered. A signed copy is attached hereto.

##### ***Priority acknowledgement***

This application claims benefit of U.S. application No. 10/257,965, which is acknowledged.

It is noted that this application also claims benefit to foreign applications in a language other than English, and no English translation is supplied or found in the present application.

##### ***Drawings***

This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Appropriate correction is required.

##### ***Specification***

The specification is objected to because it lacks the necessary reference to the prior application. A statement reading "This is a division of Application No. 10/257,965, filed 25 December 2002, now patent No. 6,555,319." should be entered following the title of the invention or as the first sentence of the specification.

#### **Rejections under 35 U.S.C. 112:**

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements/steps, such omission amounting to a gap between the elements/steps. See MPEP § 2172.01. The omitted elements/steps are: 1) dose, duration, route of administration, etc. to ensure the development of said interstitial pneumonia; 2) what steps to take or what/how to measure in order to determine the therapeutic effect of a potential remedy. The claim is further indefinite for the recitation "and screening a remedy for interstitial pneumonia" because it is unclear what is the relationship of this step to the step of "preparing an animal model", i.e., are they related; or does the screening require the use of said animal model?

Claim 28 is included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

**Prior Art:**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Arai et al. (J. Interferon & Cytokine Res., February 2000, 20 (2):217-24) discloses the effect of a combination of IL-18 and IL-2 on in vivo NK cell activation by studying mice administered with IL-18 and IL-2, and teaches that such a combined treatment resulted in a significant increase in the number of spleen NK cells and a marked enhancement of spleen NK cells activity, and contributed to inhibition of tumor metastasis without inducing significant toxicity (the abstract, page 219, the last paragraph, page 220, the left column, and Figures 3 and 5), indicating that the treatment (3 days) did not cause any significant organ disfunction/damage.

**Conclusion:**

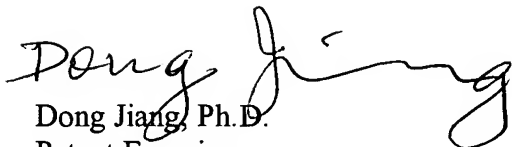
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in black ink, appearing to read "Dong Jiang", with a stylized flourish at the end.

Dong Jiang, Ph.D.

Patent Examiner

AU1646

9/20/06